REMARKS

The above-identified application has been carefully reviewed in light of the Office Action mailed September 21, 2006, which included a final rejection of all claims presented. Applicant submits that the amendments and remarks included herein show the present claims to be allowable or, if necessary, in better condition for appeal. Therefore, applicant respectfully requests that this RESPONSE UNDER RULE 116 be entered and considered on its merits.

Without conceding to the correctness of any of the Examiner's claim rejections, and in order to obtain an early allowance, clams 52, 82, 84 and 90 have been amended, and claim 79 has been canceled, without prejudice. Each of these amendments addresses one or more points raised by the Examiner in the latest (pending) Office Action. Applicant expressly reserves the right to seek patent protection for the previous claims and for any other claims supported by the above-identified application in one or more related applications.

Specifically, claim 52 has been amended to be directed to a method for treating sleep apnea, and to provide that the appliance is made of a biocompatible metal (subject matter of canceled claim 79) and is provided below the soft palate of a human or animal. Claim 82 has been amended to provide an apparatus for treating sleep apnea comprising an appliance comprising two elongated curved elements made of a biocompatible metal. Claim 84 recites that apparatus of claim 82 wherein the appliance includes only two elongated curved elements. Claim 90 has been amended to recite that the appliance is sized and structured to be placed below a soft palate of a human or

animal. Each of these amendments is fully supported by the present specification. For example, placement of the appliance below the soft palate in the oropharyngeal region is supported by the drawings, in particular Figs. 1, 24, 24a and 26 all of which show the appliance in the oropharyngeal region below the soft palate. In addition, the appliance being made of biocompatible metal is supported, for example, at page 27, lines 27-29. The amendment that the appliance includes only two elongated curved elements is supported, for example, by Fig. 7, and the description of Fig. 7, such as page 29, lines 20-23.

Claims 52-55, 66-68, 70, 71, 73-77, 79 and 80 have been rejected under 35 U.S.C. 102(b) as being anticipated by Conrad et al (U.S. Patent 6,250,307). Claims 82-90 have been rejected under 35 U.S.C. 102(e) as being anticipated by Metzger et al (U.S. Patent 2003/0149488). Claims 72, 81, 91 and 92 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Conrad et al in view of Metzger et al. Applicant traverses each of these rejections as it pertains to the present claims.

The present claims are directed to methods and apparatus for treating sleep apnea in a human or an animal having an oropharyngeal region with lateral and posterior walls.

In independent claim 52, such a method for treating sleep apnea comprises providing an appliance made of biocompatible metal below a soft palate of a human or animal in or radially outwardly from the lateral and posterior walls of an oropharyngeal region of the human or animal. The appliance so provided has at least two substantially laterally positioned elements substantially longitudinally spaced apart from each other, and is effective in treating sleep apnea.

In independent claim 82, such an apparatus for treating sleep apnea in a human or animal comprises an appliance comprising two elongated curved elements made of a biocompatible metal. In dependent claim 84, the appliance is recited as including only two elongated curved elements. Each of the two curved elements has a substantially circular dimension between a first end and a second end extending through more than 90 degrees of a circle, for example as positioned in vivo by looking at an A-P (anterior to posterior) slice through the oropharyngeal region. The two elements are coupled together at respective first and second ends and are spaced apart from each other between the first and second ends. The appliance is sized and structured to be placed in or radially outwardly from the lateral and posterior walls of an oropharyngeal region of a human or animal with the length of at least one of the elongated elements extending generally laterally across the posterior wall. The appliance, when so placed, is effective in treating sleep apnea.

To reiterate, Conrad et al does not disclose, teach or suggest the present invention. For example, Conrad et al does not disclose, teach or even suggest any method for treating sleep apnea, let alone a method for treating sleep apnea comprising providing an appliance made of a biocompatible metal below a soft palate of a human or animal in or radially outwardly from the lateral and posterior walls of an oropharyngeal region of a human or animal, as recited in the present method claims.

Conrad et al discloses no implants and methods of placing implants other than soft palate implants and methods for placing such soft palate implants in the soft palate.

The Examiner has cited a definition of the oropharyngeal region and has interpreted such definition so as to include the soft palate in the oropharyngeal region. Applicant disagrees, since this interpretation is anatomically incorrect. Applicant does not intend to include the soft palate in the oropharyngeal region. See Fig. 1 of the above-identified application and particularly reference numeral 1a which is identified as indicating the oropharyngeal region (see page 22, lines 12-15 of the present specification). The oropharyngeal region 1a in which the present appliance is placed does not include the soft palate. Rather, the oropharyngeal region in which the present appliance is placed is below the soft palate.

In view of the interpretation the Examiner has given to the oropharyngeal region and to facilitate prosecution of the above-identified application, the present method claims have been amended to clearly recite that the appliance is provided below the soft palate, which is directly contrary to the teaching of Conrad et al. The oropharyngeal region below the soft palate is separate and apart from the soft palate, and is different and distinct from the soft palate.

Thus, applicant submits that the soft palate implants of Conrad et al when placed in the soft palate, as disclosed by Conrad et al, are not located, and cannot reasonably be interpreted as being located, below the soft palate, as in the providing step recited in the present method claims.

In addition, the soft palate implants and methods of placing such soft palate implants disclosed by Conrad et al are directed toward altering the dynamic response of the soft palate to airflow pass the soft palate. See column 2, lines 23-26; column 4, lines 17-21; and column 6, lines 21-23 of Conrad et

al. Stiffening the soft palate to alter the dynamic response of the soft palate to airflow pass the soft palate to alleviate snoring, as disclosed by Conrad et al, is entirely different from and not in the least suggestive of providing an appliance below the soft palate in or radially outwardly from the lateral and posterior walls of a oropharyngeal region of a human or animal to alleviate sleep apnea, as recited in the present methods claims. Snoring and sleep apnea are different and distinct conditions. As noted above, Conrad et al does not suggest treating sleep apnea, let alone treating sleep apnea as recited in the present claims. The differences and distinctions between Conrad et al and the present claims make evident that Conrad et al actually teaches clearly, directly and expressly away from the present claims.

In view of the above, applicant submits that the present claims, and in particular, claims 52-55, 66-68, 70, 71, 73-77, 79 and 80, are not anticipated by and are unobvious from and patentable over Conrad et al under 35 U.S.C. 102(b) and 103.

Metzger et al discloses an implant formed as a braid of a plurality of polyester fibers bonded together near the ends of the polyester braid. Metzger et al discloses that the polyester braided implant is selected to induce a fibrotic tissue response, thereby stiffening the surrounding tissue.

Metzger et al does not disclose, teach or suggest the present invention. For example, Metzger et al does not disclose, teach or even suggest an appliance comprising two elongated curved elements made of a biocompatible metal, with each elongated element having a substantially circular dimension between a first end and a second end extending through more than 90 degrees of a circle with the two elements being coupled

together at respective first and second ends and being spaced apart from each other between the first and second ends, so that when the appliance is placed in an oropharyngeal region as recited in claim 82, the appliance is effective in treating sleep apnea, as recited in claim 82.

In particular, Metzger et al provides no disclosure, teaching or suggestion whatsoever that the fibers of the polyester braided implant of Metzger et al are made of biocompatible metal, as recited in the present apparatus claims. To the contrary, Metzger et al teaches only polyester fibers effective to induce a fibrotic reaction. It is this fibrotic reaction caused by the polyester fibers, not the strength of the polyester fibers, that causes the stiffening of the oropharyngeal region disclosed by Metzger et al. Metzger et al does not even suggest that the polyester fibers or braid have any strength to support the oropharyngeal region. Metzger et al relies entirely on polyester fibers inducing fibrosis to stiffen the tissue.

In direct contrast to Metzger et al, the present apparatus comprises two elongated curved elements made of biocompatible metal. Such biocompatible metal elements do not induce fibrosis in the oropharyngeal region. The above-identified application provides no disclosure of inducing fibrosis to treat sleep apnea. Rather, the present appliance is disclosed as having sufficient strength effective to support the oropharyngeal region against collapse during natural sleep (see page 11, lines 3-5).

The difference between the polyester fibers of Metzger et al and the biocompatible metal elongated elements of the present claims, and the difference between the fibrosis-inducing

mechanism of action of Metzger et al and the mechanical strain-based mechanism of action of the presently claimed apparatus are clear and convincing evidence that the present apparatus are patentably distinguished from Metzger et al.

Moreover, in view of the above differences, applicant submits that Metzger et al actually teaches away from an appliance including two elongated curved elements made of biocompatible metal, as recited in the present apparatus claims.

Therefore, applicant submits that the present claims, and in particular apparatus claims 82-90, are not anticipated by and are unobvious from and patentable over Metzger et al under 35 U.S.C. 102(e) and 103.

With regard to the rejection of claim 72, 81, 91 and 92 as being unpatentable over Conrad et al in view of Metzger et al please consider the following.

Dependent claim 72 discloses a method for treating sleep apnea in a human or animal as discussed previously with regard to independent claim 52, and further in which the at least two elements of the appliance are portions of the same structure, are substantially longitudinally spaced apart from each other, and at least one of the elements extends across the posterior wall of the oropharyngeal region.

Dependent claims 81 and 92 are directed to a method (claim 81) and an apparatus (claim 90) for treating sleep apnea in a human or animal, as discussed previously with regard to independent claims 52 and 82, respectively, and further where the appliance is made of nitinol.

Dependent claim 91 is directed to an apparatus for treating sleep apnea in a human or animal, as discussed previously with regard to independent claim 82 and further where the appliance

is made of a biocompatible metal which is an elastic spring memory material.

As discussed above, Conrad et al teaches the use of soft palate implants in the soft palate to alter the dynamic response of the soft palate to airflow past the soft palate. Conrad et al does not disclose, teach or suggest any method or apparatus for treating sleep apnea.

Metzger et al, on the other hand, discloses a flexible braid of polyester fibers (see paragraph 0042) acting to induce fibrosis (see paragraph 0067).

Conrad et al does not disclose, teach or even suggest implants or methods for using implants for placement below the soft palate in the oropharyngeal region. Rather, the Conrad et al implants are placed in the soft palate not below the soft palate in the oropharyngeal region. Metzger et al does not even suggest implants including two elements made of a biocompatible metal in which the elements are longitudinally spaced apart from each other.

Neither Conrad et al nor Metzger et al teaches or even suggests the use of implants for use below the soft palate in the oropharyngeal region of a human or animal made of a biocompatible metal which is a elastic spring memory material or nitinol. In fact, as noted above, both Conrad et al and Metzger et al teach away from such implants and the use of such implants.

Moreover, the teachings of Conrad et al directed to soft palate implants and the teachings of Metzger et al directed to a flexible braid of fibrosis-inducing polyester fibers are so different and distinct, one from the other, that one of ordinary skill in the art is provided with no motivation or incentive to

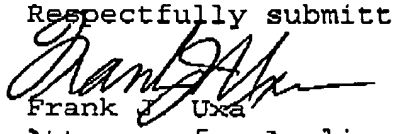
combine the teachings of these two references for any purpose, let alone for the purpose of making obvious the present invention. In addition, combining the teachings of Conrad et al and Metzger et al would not provide, and would not make obvious, the methods and apparatus recited in the present claims.

In view of the above, applicant submits that the present claims, and in particular claims 72, 81, 91 and 92, are unobvious from and patentable over Conrad et al in view of Metzger et al under 35 U.S.C. 103.

Each of the present dependent claims is separately patentable over the prior art. Each of the present dependent claims is separately patentable over the prior art, taken singly or in any combination. Thus, none of the prior art, taken singly or in any combination disclose, teach or even suggest the methods and apparatus including the additional feature or features recited in any of the present dependent claims. Therefore, applicant submits that each of the present claims is separately patentable over the prior art.

Applicant submits that this reply is fully responsive to the office action of September 21, 2006, and that the above-identified application is now in proper order for allowance. Applicant respectfully requests an early and favorable action in the above identified application.

Respectfully submitted,



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